



# Publicity and the FDA, An Update

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# Publicity and the FDA, An Update

By Shannon E. Johnson

Publicity is a powerful tool. A single Food and Drug Administration (FDA) press release announcing the dangers of a product can instantaneously alter the consumption patterns of millions of consumers. During the early 1970's, the FDA's use of publicity became the subject of heightened scrutiny by legal scholars and practitioners, calling for guidelines and judicial review to prevent unwarranted damage from the potent instrument.<sup>1</sup> This paper will reexamine the FDA's use of publicity in light of the past 20 years. Following a general background, the discussion will update the status of agency policy and judicial attitudes towards publicity, highlight current implications, and offer recommendations.

## Authority for Publicity

The Food, Drug and Cosmetic Act gives the FDA general authority to shield consumers from dangerous and mislabeled foods, drugs, medical devices and cosmetics.<sup>2</sup> The agency's ability to protect the public hinges on its power to remove defective products from the market as quickly as possible. Due to the costly and time-consuming nature of the FDA's two main tools, seizures<sup>3</sup>

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<sup>1</sup>See Ernest Gellhorn, *Adverse Publicity By Administrative Agencies*, 86 HARV. L. REV. 1380 (1973); Recommendation 73-1: Adverse Agency Publicity, 38 Fed. Reg. 16839; Scott M. Fisher, *Publicity and the FDA*, 28 FDC L.J. 436 (1973); Richard S. Morey, *Publicity as a Regulatory Tool*, 30 FDC L.J.469 (1975); Edward L. Smith, *The Cranberry Scare and Cabinet Immunity*, 16 FDC L.J. 209 (1961).

<sup>2</sup>Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. §§301-395.

<sup>3</sup>*Id* at §334.

and injunctions,<sup>4</sup> which require court approval, the use of publicity has become an appealing alternative.<sup>5</sup> The FDA is one of the few agencies with specific statutory authority to issue publicity.<sup>6</sup> Section 705(a) of the Federal Food, Drug and Cosmetic Act<sup>7</sup> requires the agency to publish reports of all judgments rendered under the act. More relevant to our discussion is Section 705(b), which states:

The Secretary may also cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health, or gross deception of the consumer. Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department.<sup>8</sup>

The legislative history of the statute demonstrates a congressional intent to confine the agency to the limited exceptions of “imminent danger to health and gross deception of the consumer.” The first draft of the statute would have allowed the Secretary to report all proceedings, even at the initial stage, and to disseminate “such information regarding any food, drug, or cosmetic as he deems necessary in the interests of public health and for the protection of the consumer against fraud.”<sup>9</sup> The third draft of the Act tempered this wording, adding a clause forbidding the release of information naming specific brands of food, drugs and cosmetics except in cases of imminent danger or gross consumer deception.<sup>10</sup> The accompanying record suggests this clause was to

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<sup>4</sup>*Id* at §332.

<sup>5</sup>This article only examines the affirmative issuance of publicity by the FDA, and does not address the release of agency information or records to comply with the Freedom of Information Act, 5 U.S.C. §552.

<sup>6</sup>Gellhorn, *supra* note 1, at 1408.

<sup>7</sup>21 U.S.C. §375 (1988).

<sup>8</sup>*Id.*

<sup>9</sup>S. 1944, June 6, 1933.

<sup>10</sup>S. 2800, March 15, 1934.

protect companies from exposure to pre-judgment censure.<sup>11</sup>

The agency's statutory authority to issue publicity has expanded in recent years. In 1988, Congress added a broader statement of FDA power to issue public information. Section 393 of the Federal Food, Drug and Cosmetic Act now lists among the general powers of the Commissioner: "conducting educational and public information programs relating to the responsibilities of the Food and Drug Administration...."<sup>12</sup>

#### Benefits of Publicity

Admittedly, the benefits of publicity are quite substantial. A press release or a news conference requiring very little time or money can alert the entire nation to the hazards of a product. Additionally, the FDA can use publicity to produce "maximum compliance with minimum resources," as manufacturers who fear adverse publicity will "voluntarily" recall their products to stave off agency involvement and protect consumer confidence in their product.<sup>13</sup> Enforcement statistics demonstrate that recalls have been on the rise, while more formal sanctions such as seizures and criminal prosecutions have declined. In 1939, the FDA instituted 626 prosecutions and 1,861 seizures, but made no recalls.<sup>14</sup> By 1989, the number of prosecutions and seizures had fallen to 16 and 144 respectively, while the number of recalls had risen to 370.<sup>15</sup>

The FDA is clearly aware of the power its publicity can have over industries, and has publicly acknowledged this influential role. The agency has

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<sup>11</sup>Sen. Rep. No. 493 (March 15, 1934).

<sup>12</sup>21 U.S.C. §393.

<sup>13</sup>JAMES T. O'REILLY, FEDERAL INFORMATION DISCLOSURE, §25.02 (2d ed. 1995).

<sup>14</sup>PETER BARTON HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW 1205 (2d ed. 1991).

<sup>15</sup>*Id.*

noted that even before it completes the procedural steps involved in banning a product, manufacturers have often already changed their behavior based on consumer reaction to FDA's initial announcement. For example, in a proposal to ban prosthetic hair fibers, the agency noted that, due to national publicity of the agency's press releases, virtually all manufacturers had already ceased producing and distributing the device.<sup>16</sup> Similarly, when banning the use of sulfites in fresh potatoes, FDA said potato processors had already changed their technique due to adverse publicity.<sup>17</sup> Thus, publicity is appealing to the FDA because it has provided a fast and effective way to carry out its mission of protecting the public.

#### Drawbacks of Publicity

While publicity can be an efficient tool for promoting public health and safety, it can also be extremely damaging to private parties. Because decisions to issue publicity do not pass through formal procedures, negative announcements often come without notice and without adequate time for rebuttal. Due to the public's sensitivity to health risks associated with food and medicine, adverse publicity issued by the FDA has bankrupted companies and devastated industries. For instance, a single public warning by the Secretary of Health, Education and Welfare (HEW) in 1959 caused millions of dollars in damages to the nation's cranberry growers. The so-called "cranberry scare" began a few weeks before Thanksgiving when Secretary Arthur Fleming announced that cranberries from Washington and Oregon might contain a weed killer found to

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<sup>16</sup>The proposed ban was thus designed to preventing future marketing of the product, as current marketing had already ceased. 48 Fed. Reg. 25126, 25136 (1983).

<sup>17</sup>55 Fed. Reg. 9826, 9831 (1990).

cause cancer in laboratory rats, even though no specific scientific evidence suggested that cranberries would cause the same effects in humans.<sup>18</sup> The HEW later discovered that the most of the cranberries were safe, but the holiday had already passed with 99 percent of the year's crop unsold.<sup>19</sup> The government later paid \$10 million for losses suffered by the growers of the uncontaminated cranberries.<sup>20</sup> Absent the voluntary indemnification by the government, an extremely rare occurrence, the growers would have been without remedy.<sup>21</sup> Other illustrative examples of crippling publicity include an overstated harm of botulin in Bon Vivant soup which led to bankruptcy and a sharp decline in sales of all brands of canned soups,<sup>22</sup> and a \$6.4 million loss sustained by fruit growers due to the FDA's statement that the artificial sweetener cyclamate caused cancer in laboratory animals.<sup>23</sup> These false alarms demonstrate the negative consequences of FDA publicity based on erroneous data or overstated risk.<sup>24</sup>

Not only does adverse publicity come without formal action or notice, it also leaves disparaged companies without recourse for their losses because courts are unlikely to grant relief. To begin with, courts have established that due process does not require the FDA to afford manufacturers a hearing before disseminating warning information about their products.<sup>25</sup> In addition, sovereign immunity usually shields the FDA from liability for libel and slan-

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<sup>18</sup>Gellhorn, *supra* note 1, at 1408.

<sup>19</sup>*Id.*

<sup>20</sup>*Id.*

<sup>21</sup>The lack of judicial remedy is discussed on page 6.

<sup>22</sup>See Gellhorn, *supra* note 1 at 1413.

<sup>23</sup>The discussion of this incident begins on page 7.

<sup>24</sup>A separate drawback of negative publicity is that it may unfairly prejudice a defendant in a trial or trial-like administrative hearing. See, e.g., *United States v. Abbott Labs*, 505 F.2d 565 (4th Cir. 1974), cert denied, 420 U.S. 990.

<sup>25</sup>*Hoxey Cancer Clinic v. Folsom*, 155 F. Supp. 376 (D.D.C. 1957).

der suits. The Federal Tort Claims Act (FTCA), which generally waives the federal government's sovereign immunity with respect to tort claims for monetary damages, includes a "discretionary function exception" retaining immunity with respect to "any claim...based upon the exercise or performance, or failure to exercise or perform a discretionary function or duty..., whether or not the discretion involved be abused."<sup>26</sup> The only way around the sovereign immunity bar is to convince Congress to pass a private bill permitting a waiver of immunity for a U.S. Court of Claims suit. This requires enormous political pressure and is an extremely lengthy process, as was demonstrated by the California Canners & Growers Association's 14-year battle for government compensation that ended in vain.<sup>27</sup> Generally, FDA-issued publicity is beyond the reach of a liability action, even if it is found to be erroneous.<sup>28</sup>

Even when a case does not fall under the discretionary function exception, a court may reject a suit based on a failure to satisfy the elements of a tort claim. For example, many FDA announcements involve a general substance such as cranberries or cyclamates, and do not target a specific manufacturer or product name. However, an essential element in a product disparagement claim is specificity of the product addressed,<sup>29</sup> and thus claims by individual companies based on general announcements usually fail. Courts have also been receptive to the FDA argument that economic harm results from independent

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<sup>26</sup>28 U.S.C.A. §2680(a).

<sup>27</sup>The discussion of this incident begins on page 7.

<sup>28</sup>*See, e.g. Fisher Bros. Sales, Inc., et al, v. U.S.*, 46 F.3d 279 (1995), discussed further on page 8.

<sup>29</sup>*See, e.g., Ajay Nutrition Foods Inc. v. FDA*, 378 F. Supp. 210 (D.N.J. 1974), *aff'd* 513 F.2d 625 (3rd Cir. 1975).

consumer decisions, not agency publications. In *Pharmaceutical Manufacturers Association v. Kennedy*,<sup>30</sup> the FDA contended that it intended its comparison of generic and brand name drugs merely as an educational guide for consumers, not as a charge for industry action,<sup>31</sup> while the Association maintained that the guide was inaccurate and would cause consumers to switch to cheaper generic brands.<sup>32</sup> The court sided with the FDA, finding that any effect on brand name drug sales resulted from independent public choice.<sup>33</sup> Thus, on the whole, courts have not granted relief to companies devastated by FDA publicity.

#### Recent Judicial Action

In recent years, courts have followed their usual course of denying judicial recourse for incorrect agency publicity. Since the 1959 cranberry episode, Congress has passed only one piece of legislation allowing court review of damaging publicity. A 1984 bill admitted federal liability for losses sustained by fruit growers resulting from the FDA's "erroneous publicity and misrepresentations" that the artificial sweetener cyclamate caused cancer in laboratory animals, and called on the U.S. Claims Court to estimate the damages.<sup>34</sup> In response, the court found that, despite the absence of legal liability under the FTCA, Congress had a "moral obligation" to compensate the California Cannery and Growers Association for \$6.4 million in losses from the damaging announcement.<sup>35</sup> The court's report was reversed, however, in 1986 when a review panel concluded

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<sup>30</sup>471 F. Supp. 1224 (D.Md. 1979).

<sup>31</sup>*Id* at 1225.

<sup>32</sup>*Id* at 1230.

<sup>33</sup>*Id* at 1231.

<sup>34</sup>S.1894 (95th Cong., 1st Sess.).

<sup>35</sup>*California Cannery & Growers Assoc. v. U.S.*, 7 Cl. Ct. 69 (1984).



that the growers had no legal or equitable basis for their claim because (a) the statements made by the government officials were not arbitrary or capricious, and (b) the fruit growers did not show that the statements actually caused their losses.<sup>36</sup> This ruling seems to imply that courts may not look favorably on attempts to circumvent the discretionary function exception through unprecedented equitable arguments such as “moral obligations.”

The most recent case involving FDA’s affirmative issuance of publicity, a 1995 decision rejecting Chilean fruit growers’ tort suit against the FDA,<sup>37</sup> also demonstrates the continued reluctance of courts to respond to the complaints adverse publicity victims. A group of fruit growers alleged that a laboratory report citing the presence of cyanide in two Chilean grapes was negligently prepared and violated established procedures. Based on the alleged faulty report and with knowledge of a conflicting report from another lab, the FDA Commissioner issued an order refusing entry of Chilean fruit into the country and issued a press release warning consumers of the cyanide and encouraging growers to remove fruit from their shelves. The fruit growers contended that, but for the announcement of the negligent investigation results, the Chilean fruit business for the spring season of 1989 would not have been destroyed.<sup>38</sup> The majority held that because the plaintiffs’ claims criticized the Commissioner’s decision, their suit was barred by the discretionary function exception to the FTCA, which was “designed to protect policymaking by politically accountable branches of government from interference in the form of ‘second-guessing’ by

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<sup>36</sup> *California Cannery & Growers Assoc. v. U.S.*, 9 Cl. Ct. 774 (1986).

<sup>37</sup> *Fisher Bros. Sales, Inc., et al. v. U.S.*, 46 F.3d 279 (1995).

<sup>38</sup> *Id.* at 283.

the judiciary.”<sup>39</sup> While the decision reinforced the government’s protection under the discretionary function exception, the six-judge dissent suggested a way to evade the bar. After conceding that the decision to test and ban the fruit was a discretionary choice, the dissenters asserted that once the government makes a policy decision, it must proceed with due care in the implementation of that decision. Thus, while the decision to test the fruit is beyond the reach of the courts, the negligent performance of the tests is still subject to judicial reprimand, the dissenters reasoned.<sup>40</sup> The six-judge approval of this reasoning may bode well for future plaintiffs seeking compensation for faulty publicity, although the weight of precedence against judicial review of discretionary decisions is quite strong. It is worth noting that no other decision has replicated this court’s reasoning.

Only one recent majority opinion suggests judicial sympathy for targets of adverse publicity, and even its rebuke is somewhat indirect. In 1990, the U.S. District Court for the District of Columbia held that elastic netting manufacturers entitled to a hearing on a Food Safety and Inspection Service (FSIS) ban of their product as an unauthorized food additive.<sup>41</sup> Of particular importance was the court’s criticism of FSIS for issuing a press release on the ban, without prior notice to the manufacturers. The announcement virtually destroyed the industry: “In one swooping statement, without notice or the opportunity to be heard, plaintiffs lost their livelihood, built over [a] 25 to 30

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<sup>39</sup> *Id.*

<sup>40</sup> *Id.* at 291.

<sup>41</sup> *C & K Manufacturing & Sales Co., et al. v. U.S.D.A.*, 749 F. Supp. 8 (D.D.C. 1990).

year period...plaintiffs, frankly, deserve better from their Government.”<sup>42</sup> This reprimand, while directed here at the FSIS, could be viewed as a warning for all agencies to proceed with caution when issuing adverse publicity. Unfortunately, no other recent cases have cited or endorsed this court’s position. Thus, in general, courts continue to refuse the claims of manufacturers who suffer the effects of negative publicity.

#### Recent Agency Response to Criticisms

As previously mentioned, legal scholars of the 1970’s criticized the FDA and other agencies for their imperfect use of publicity. In response to suggestions by Professor Ernest Gellhorn,<sup>43</sup> the Administrative Conference of the United States recommended a set of guidelines for agencies to follow when considering the use of negative publicity:

1. Publicity should be factual in content and accurate in description.
2. For publicity related to regulatory investigations or pending trial-type proceedings:
  - (a) Publicity can be used, preferably with advance notice, in cases of significant risk to the public health or substantial threat of economic harm.
  - (b) Publicity should be used to provide notice to persons who are affected or would be interested in participating in a particular proceeding.
  - (c) Where leaks, FOIA disclosures, or other sources are likely to generate publicity, agencies should use their own publicity to advance public understanding or accuracy of the media coverage.
3. All other investigations or proceedings should only be publicized after precautions are taken as to the publicity’s accuracy and the agency is sure that publicity will fulfill an authorized purpose.
4. Allegations should be labeled as allegations, subject to later proof, and, where possible, respondents given reasonable advance notice.
5. Agencies should issue retractions and corrections in the same manner as the original publicity, when requested, if the person affected shows the publicity to have been erroneous or misleading.<sup>44</sup>

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<sup>42</sup> *Id* at 14.

<sup>43</sup> Gellhorn, *supra* note 1.

<sup>44</sup> Recommendation 73-1, Adverse Agency Publicity (1973), summarized in O’Reilly, *supra* note 13.

The Department of Health Education and Welfare, of which the FDA is a departmental component, codified these regulations in 1976,<sup>45</sup> taking a positive step towards confining adverse publicity. However, the FDA has never formally endorsed the recommendations. The agency's main response to the recommendations, a proposal outlining internal publicity policy,<sup>46</sup> was never finalized. Nor has the agency proposed or issued other guidelines regarding its use of publicity, even though it has diligently codified most of its other general administrative practices. The agency has published a comprehensive set of regulations governing its procedures, which detail the operation of formal hearings, advisory committees, legislative-type hearings, informal hearings, and delineate general practices and standards of conduct,<sup>47</sup> but do not address adverse publicity. In 1993, the agency offered a vague behind-the-scenes look at its procedure for releasing information to the public.<sup>48</sup> The Office of Public Affairs claimed that its press releases and *Talk Papers* come from the combined efforts of:

1. the experts in FDA centers, who provide technical information on an issue;
2. the press skills from the Office's press staff to convert the technical information into language of news people; and
3. the front office, which approves the content of either piece.<sup>49</sup>

The FDA has also noted that the Public Health Service and Department of Health and Human Services often scrutinize its press releases.<sup>50</sup> Neither of these descriptions of the public announcement procedure gives any insight

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<sup>45</sup>45 C.F.R. Part 17 (1976).

<sup>46</sup>Administrative Practices and Procedures: Publicity Policy, 42 Fed. Reg. 12436 (March 4, 1977).

<sup>47</sup>42 Fed. Reg. 15553 (March 22, 1977).

<sup>48</sup>McLearn, *supra* note 4, at 25.

<sup>49</sup>*Id.*

<sup>50</sup>*Id.*

into the criteria the FDA uses to determine when potentially damaging adverse publicity is appropriate or what level of certainty about risk the FDA requires before announcing the alleged hazards of a particular product. Furthermore, the agency has not explained how it plans to respond to HEW's call for a routine system of prior notification to manufacturers and guidelines for retractions and corrections. Therefore, the FDA has failed to heed the suggestions of HEW and has avoided its duty to establish comprehensive guidelines ensuring consistent and careful use of adverse publicity.

#### Current Implications of Adverse Publicity

The repercussions of negative publicity have becoming more acute in this so-called "Information Age." In pre-television, pre-fax machine days, FDA release of health information took longer to reach a national audience. Common methods of transmitting information included mailing press releases to medical journals and other publications,<sup>51</sup> and posting notices in local post offices in emergency situations.<sup>52</sup> Even with a speedier transmission of information through a press conference, telephone call or wire service, a daily newspaper would not be able to publish FDA released information until at least the following day and would thus leave some time for the FDA to retract faulty statements before publication. Today, twenty-four hour news networks such as CNN can report the news as soon as its received. In short, modern technology means bad news travels faster.

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<sup>51</sup>Wallace F. Janssen, *Public Information Under the Federal Food, Drug and Cosmetic Act*, IV, 12 FDC L.J. 566, 572 (1957).

<sup>52</sup>As was used to notify consumers of fraudulent cancer treatment claims in *Hoxsey Cancer Clinic v. Folsom*, 155 F. Supp. 376 (D.D.C. 1957).

Moreover, the FDA has taken full advantage of the latest technology to expand its media influence. The agency's Office of Public Affairs has grown over the years, and by 1993 , it consisted of four staffs handling 300 telephone inquiries per day and issuing approximately 50 press releases and 100 *Talk Papers* (responses to inquiries about news stories) per year.<sup>53</sup> Agency publications such as the *FDA Consumer*, which provides news summaries and feature stories on agency actions, now reach a circulation of more than 25,000 paid subscribers.<sup>54</sup> In addition, the FDA has increased the speed and compass of its information dissemination by establishing a free electronic bulletin board system that contains up-to-the-minute news releases, weekly recall lists, approvals lists, congressional testimony, speeches and more. The agency now provides this extensive collection of data on its Internet web site,<sup>55</sup> which gives worldwide access to FDA announcements at the touch of a button. In addition, the public affairs office distributes video news releases via satellite to as many as 700 television stations.<sup>56</sup> Consequently, today's FDA announcements reach a much larger audience in a much shorter amount of time.

Some might suggest that the speed and pervasiveness of current information technology actually protects manufacturers against erroneous adverse publicity because the government has the ability to instantly retract or qualify its statements. This argument wrongly assumes that the public will heed such retractions when, studies show that "Exoneration rarely commands the same

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<sup>53</sup>Donald C. McLearn, *FDA's Office of Public Affairs*, 48 FOOD & DRUG L.J. 23,24 (1993).

<sup>54</sup>*Id* at 27.

<sup>55</sup>The Internet site is: <http://www.fda.gov>.

<sup>56</sup>McLearn, *supra* note 4, at 28.

public attention as a charge of wrongdoing.”<sup>57</sup> One report found that more than three times the coverage is given to government assertions of risk than to assertions of the absence of risk.<sup>58</sup> A good illustration of this principle occurred when the Federal Trade Commission released and then retracted damaging publicity about an antifreeze product. The negative statements were published in 160 newspapers with 20 front page stories, while the agency’s admission of error received no front page attention and was seen in only 80 papers.<sup>59</sup> Thus, the instant and often unretractable effects of modern media outlets have heightened the damaging potential of adverse agency publicity.

#### Recommendations

As previously mentioned, the combined lack of established agency procedures for issuing adverse publicity and judicial review leaves manufacturers with no recourse from damaging, and sometimes devastating, announcements. The government has a duty to monitor carefully its use of adverse publicity to ensure the viability of the food and drug industry that constitutes one-quarter of our national economy. The financial demise of just one food or drug manufacturer can mean the loss of thousands of jobs and billions of dollars. The best way to limit the number of damaging mistakes is for the agency to police its use of adverse publicity through the promulgation of clear and consistent internal guidelines. Judging from the FDA’s prior failure to formalize its publicity policy, however, the odds for intra-agency improvements seem slim.

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<sup>57</sup> *Rushford v. Civiletti*, 485 F. Supp. 477, 479 (D.D.C. 1980).

<sup>58</sup> Frank B. Cross, *The Public Role in Risk Control*, 24 ENVIRONMENTAL LAW 887, 906 (1994).

<sup>59</sup> JAMES T. O’REILLY, *FEDERAL INFORMATION DISCLOSURE*, §25.01 (2D ED. 1995).

Turning to another possible remedy, external control, Professor Gellhorn has suggested that Congress enact express statutory authority for limited judicial review of agency publicity practices, and amend the Federal Tort Claims Act to allow compensatory relief for victims of unfair and harmful agency publicity.<sup>60</sup> Congress has largely ignored these recommendations during the past twenty years, and has never specifically addressed adverse publicity by the FDA during that time. Congress may fear that holding the government liable for potentially large damage awards may temper the FDA's zealous efforts to ensure public safety. Given inconclusive data on a food or drug risk, the threat of litigation could color the agency's decision on whether to wait for future test results, thus possibly imperiling public health. In addition, judicial review may not even be the most desirable way to help companies recover negative publicity losses because lawsuits are slow and expensive and outcomes are always uncertain.

Since prior recommendations have been discarded and may not even be the best solution for the current problem, it's time to look for new solutions. There may be less intrusive approaches that can strike a balance between the FDA's need to alert the public and the food and drug industry's right to compensation for government mistakes. Instead of inhibiting FDA's decision-making process or opening the door to potentially large damage suits, the government could offer low interest loans or tax breaks to industries struggling to recover from the effects of adverse publicity. This way, the government could

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<sup>60</sup>Gellhorn, *supra* note 1, at 1432.



unabashedly warn the public about potential dangers, but if the announcements turn out to be unfounded, the government could help the industry survive the storm. Congress could pay for this scheme by charging an application fee to companies seeking FDA pre-market approval of new drugs (and possibly for food and color additives), just as the U.S. Patent and Trademark Office charges a patent application fee. While it is true that only those companies whose products require pre-market approval may bear the cost of user fees that all manufacturers benefit from, it is precisely those companies that reap the greatest benefit from FDA approval of profitable new drugs. For example, investors expect Eli Lilly's schizophrenia drug, approved last fall, to provide \$1 billion in sales by the year 2000.<sup>61</sup> In addition, it is doubtful that an application fee would have any deterrent effect on new drug applications, given the potential windfall that the marketing of new drugs provides.

An alternative approach would be to spread the cost to consumers through an excise tax on food and drug products. The government can justify the small charge to the public by noting the daily benefits consumers receive from continual evaluation and announcement of the safety status of various foods and drugs. The FDA already uses a similar tax in the area of childhood vaccines whereby an excise tax levied on product sales is used to compensate children who suffer injury from vaccination.<sup>62</sup>

These suggestions would require substantially more development and thus their feasibility is not the intended focus of this paper. The presentation of

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<sup>61</sup> *Moneyline* (CNN cable report, October 1, 1996).

<sup>62</sup> National Childhood Vaccine Injury Act of 1986, 100 Stat. 3743, 3755 (codified at 42 U.S.C. §300aa-1 *et seq*).

these unconventional approaches merely seeks to demonstrate that, with some creativity, it is possible to reach a solution that satisfies everyone's needs: the FDA can compensate victims of adverse publicity without unduly restricting the ability of the agency to carry out its mission of protecting lives.

### Conclusion

When the Food and Drug Administration proposed guidelines on the agency's use of publicity,<sup>63</sup> pundits predicted that, "The regulated community will have either a model agency to admire or another disappointment."<sup>64</sup> Twenty years later, the FDA still has not formalized a coherent policy towards the exceedingly powerful and often devastating tool of publicity, and courts continue to reject pleas for compensation. All the while, the expansions and innovations in media technology have drastically increased the power of publicity as a regulatory tool. If the FDA continues to reap the benefits of the modern information age, it must also address the modern repercussions.

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<sup>63</sup>Administrative Practices and Procedures: Publicity Policy, 42 Federal Register 12436 (March 4, 1977).

<sup>64</sup>James T. O'Reilly, *supra* note 59, at §25.02.